Remarks

The Office Action mailed 18 August 2003 has been received and reviewed. Claims 10, 11, and 23 having been amended, the pending claims are claims 1-21 and 23.

Claims 10 and 23 have been amended to remove the colorant Brilliant green, and claim 11 has been amended to remove the colorant Crystal violet. These amendments have been made solely to advance prosecution of this application.

Reconsideration and withdrawal of the rejections are respectfully requested.

Interview Summary

Applicant thanks the Examiners for the courtesy extended during a telephone interview held December 11, 2003, during which Examiner Chorbaji, his supervisor, Robert Warden, Ann Mueting, David Read, Mary Hurlocker, and Kathleen Franklin participated in discussion of the application and the outstanding Office Action.

A subsequent review of the Interview Summary Record, a copy of which was faxed to Applicants' Representative, Ann Mueting, makes it clear that Applicant's Representative and Applicant did not succeed in helping the Examiner understand the invention. Applicant herein points out the following corrections and clarifications to the Interview Summary Record prepared by the Examiner.

The Examiner states that "[w]ith respect to independent claims 1, 10, and 23; applicant explained that the hydrogen peroxide in Davies et al is not reacting instead it is inactivated by a change of the pH, whereas in the invention hydrogen peroxide actually reacts with the dye composition." This statement is not accurate. What was discussed, using phenolphthalein as an example of a pH indicator, is that in Davies et al. the hydrogen peroxide is not reacting with the pH indicator, but the pH indicator is changing color as a consequence of the inactivation of the hydrogen peroxide, which causes a change in the pH. Davies et al. disclose a pH indicator that detects a change in pH caused by the inactivation of the hydrogen peroxide, and indicates the pH change by a change in color. It is not accurate to state that the hydrogen

peroxide in Davies et al. is inactivated by the change in pH. This discussion concerned the disclosure of phenolphthalein specifically, and pH indicators generally, not necessarily any other indicators in Davies et al. that are not acting as pH indicators.

Following this, the Examiner states, "[a]lso, applicant indicated that Davies et al. indicator is in a liquid state whereas his invention is in a vapor state. However, independent claims 1, 10, and 23 do not recite such limitations." First, Applicant points out that the indicator of Davies et al. is not in the liquid state; rather it is included in a solution which includes the indicator, a disinfecting agent, and an inactivating agent. Furthermore, it is not clear what "his invention is in the vapor state" means. If the Examiner is referring to the indicator of the Applicant's invention, this is not true. If the Examiner is referring to the sterilant used with the indicator of Applicant's invention, this is true. In a method of the present invention, it is the hydrogen peroxide sterilant that is in the vapor state[1]. Applicant points out that claims 1, 10, and 23 recite, "[a] hydrogen peroxide sterilization indicator comprising a substrate and an indicator composition disposed thereon . . . " (emphasis added). It is not clear to Applicant how this could be interpreted as either a liquid state or a vapor state. Furthermore, it is not clear what "limitations" the Examiner referred to when stating that independent claims 1, 10, and 23 do not recite "such limitations."

Also, it is Applicant's understanding that if claim 11 were amended to remove "Crystal violet," claim 11 would be allowable, and if claims 1, 10, and 23 were amended to remove "Brilliant green," these claims would be allowable. Applicant agrees that it was stated that Applicant would consider these statements by the Examiner, but did not agree during the telephone interview to make such amendments.

Finally, in a telephone call with the Examiner as a follow up to the interview, it was further suggested to Applicant's Representative, Ann Mueting, that the Examiner apparently

1. So as to prevent further confusion of the issue, the method claim recites exposing an article to be sterilized and a hydrogen peroxide sterilization indicator to a sterilant vapor consisting essentially of hydrogen peroxide, although the sterilization indicator claims are not so limited. Applicant's Representative did ask, during the telephone interview, if it would be helpful to amend the sterilization indicator claims to recite a sterilant vapor; however, the

does not fully appreciate the present invention. In light of this, a follow-up telephone interview with the Examiner and his supervisor, Robert Warden, is earnestly requested.

Applicant's Invention

Applicant's invention includes hydrogen peroxide sterilization indicators (claims 1, 10, and 23) and methods of monitoring a hydrogen peroxide sterilization process including a hydrogen peroxide sterilization indicator (claim 11). The indicators of claims 1, 10, and 23 include: a substrate, and an indicator composition disposed thereon. The indicator composition includes at least one colorant selected from a group of colorants. As a result of contact with hydrogen peroxide used in, for example, a hydrogen peroxide vapor sterilization process, "the colorants change color, and even become colorless, thereby providing an indication of the presence of hydrogen peroxide" (specification, page 3, lines 19-21).

That is, in the present invention, an indicator composition, which includes at least one colorant, is disposed on a substrate to provide a hydrogen peroxide sterilization indicator that indicates the presence of the sterilant, hydrogen peroxide. The sterilant, e.g., hydrogen peroxide, may be in the vapor phase (claim 11); however, there is no recitation in the claims that the sterilization indicator (which includes an indicator composition that further includes at least one colorant) is in the vapor phase.

The 35 U.S.C. §103 Rejection

A. Claims 1-10 and 21

The Examiner rejected claims 1-2, 4-6, and 9-10 under 35 U.S.C. §103(a) as being unpatentable over Ignacio et al. (U.S. Patent No. 6,287,518, hereinafter "Ignacio et al. '518") in view of Davies et al. (U.S. Patent No. 4,863,627); claims 3, 7, and 21 under 35 U.S.C. §103(a) as being unpatentable over Ignacio et al. (Ignacio et al. '518) in view of Davies et al. (U.S. Patent No. 4,863,627) and further in view of Bealing et al. (U.S. Patent No. 5,990,199); and claim 8

Examiner did not clearly positively respond to the inquiry.

under 35 U.S.C. §103(a) as being unpatentable over Ignacio et al. (Ignacio et al. '518) in view of Davies et al. (U.S. Patent No. 4,863,627) and further in view of Bealing et al. (U.S. Patent No. 5,990,199) and Barrett (U.S. Patent No. 5,955,025).

Applicant respectfully traverses these rejections.

Claims 1-10 and are not obvious under 35 U.S.C. §103 over the cited art.

"When applying 35 U.S.C. § 103, the following tenets of patent law must be adhered to:

(A) The claimed invention must be considered as a whole;
(B) The references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination;
(C) The references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention; and
(D) Reasonable expectation of success is the standard with which obviousness is determined." M.P.E.P. § 2141 (citations omitted).

Ignacio et al. '518

Ignacio et al. '518 discloses a sterilization monitor that includes a substrate and a monitor composition. The monitor composition includes a colorant and a halogen source. The sterilization monitor may be used to monitor a sterilization process that involves a peracid (Ignacio et al. '518, Abstract). Ignacio et al. '518 further discloses a method of monitoring a sterilization process involving a peracid.

The monitor composition apparently serves a function in the invention of Ignacio et al. '518 similar to the function of the indicator compositions of the present invention. The monitor compositions of Ignacio et al. '518 include colorants susceptible to halogenation in the presence of a peracid (Ignacio et al. '518, col. 2, lines 22-25); however, it is noted that the colorants of Ignacio et al. '518 included in the monitor compositions are also referred to as a dye that is "susceptible to halogenation in the presence of a halogen source and a peracid, and changes color as a result of the halogenation" (Ignacio et al. '518, col. 3, lines 10-12). The

sterilization process of Ignacio et al. '518 includes a peracid, and may further include additional sterilants, such as hydrogen peroxide (Ignacio et al. '518, col. 5, lines 53-55).

Davies et al.

Davies et al. disclose a contact lens disinfecting composition in solid form that is added to water. The disinfecting composition includes a contact lens disinfecting agent, which is a source of hydrogen peroxide when in water (Davies et al., Abstract, emphasis added). The disinfecting composition further includes an inactivating agent for the disinfecting agent and a color change indicator such that in use a visible color change occurs upon inactivation of the disinfecting agent (Davies et al., col. 3, lines 9-18). The disinfecting agent must be able to be rendered ophthalmically acceptable (Davies et al., col. 3, lines 13-14), and the indictor must also be ophthalmically acceptable, at least after the inactivation of the disinfecting agent (Davies et al., col. 3, lines 25-27).

That is, the disinfecting agent, which is a source of hydrogen peroxide in water, is combined with the indicator, the indicator changing color such as do the colorants of the present invention. In Davies et al., thus, the indicators are in solution as well as are the disinfecting agents. There is no disposition of a composition on a substrate, such as is claimed in the sterilization indicators of the present invention.

1. There is no motivation to combine the teachings of Ignacio et al. '518 with the teachings of Davies et al., as Davies et al. is drawn to nonanalogous art.

Ignacio et al. '518 teach monitoring a sterilization process that uses a vapor including a peracid (e.g., peracetic acid) (Ignacio et. al. '518, col. 1, lines 24-25). The monitor composition undergoes a distinct color change when exposed to peracid vapor (Ignacio et al. '518, col. 2, lines 65-66). Although Ignacio et al. '518 indicate that the sterilization process may include the use of other sterilants, such as hydrogen peroxide, such use is in addition to a peracid (Ignacio et al., col. 5, lines 53-56).

Davies et al., on the other hand, disclose a contact lens disinfecting composition including a hydrogen peroxide disinfecting agent, a color change indicator, and an inactivating agent (Davies et al., col. 3, lines 9-18), hydrogen peroxide being "particularly attractive in that its decomposition product is simply water" (Davies et al., col. 1, lines 41-43). The disinfecting agent must be able to be rendered ophthalmically acceptable upon completion of the disinfection process (Davies et al., col. 3, lines 9-18).

To be able to rely on a document in making an obviousness rejection, the document must be analogous art. That is, the document "must either be in the field of applicant's endeavor, or, if not, then be reasonably pertinent to the particular problem with which the inventor was concerned." In re Oetiker, 977 F.2d 1443, 1446, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992). Furthermore, for a document to be "reasonably pertinent" it "logically would have commended itself to an inventor's attention in considering his problem." In re Clay, 966 F.2d 656, 659, 23 USPQ2d 1058, 1061 (Fed. Cir. 1992). It is submitted, for reasons discussed herein, that Davies et al. is neither in the field of Applicant's endeavor, nor is it reasonably pertinent to Applicant's problem solved by the present invention. Applicant, therefore, respectfully asserts that one skilled in the art would not be motivated to combine the teachings of Ignacio et al. '518 with those of Davies et al., as the disclosure of Davies et al. is drawn to nonanalogous art.

Ignacio et al. '518 is concerned with the field of sterilization processes and sterilization monitors (useful, for example, for sterilization of medical instruments and parenteral drugs prior to use (Ignacio et al. '518, col. 1, lines 9-10)), while Davies et al. disclose solutions including a disinfecting agent, an inactivating agent, and indicators that change color (useful for ophthalmic lenses). Further, Ignacio et al. '518 teach a peracetic acid sterilization process, while the disinfecting solutions of Davies et al. require a disinfecting agent capable of being rendered opthalmically acceptable (Davies et al., col. 3, lines 9-14). There is no teaching or suggestion in either Ignacio et al. '518 or Davies et al. that a peracetic acid sterilization process could be rendered ophthalmically acceptable. Further, the indicator of Davies et al. that change color must also be ophthalmically acceptable, at least upon inactivation of the disinfecting agent. There is

no teaching or suggestion that the sterilization monitors including monitor compositions of Ignacio et al. '518 are ophthalmically acceptable. Thus, it is submitted that one skilled in the art would logically have no reason to look to the peracetic acid sterilization monitors and processes of Ignacio et al. '518 to solve the problem of disinfecting contact lenses wherein the indicators and disinfecting agent must be, or be able to be rendered, ophthalmically acceptable.

Additionally, with regard to claim 6, Applicant points out that the Examiner, at item 3, lines 7-8 (page 2 of the Office Action) and page 3, lines 11-12, stated that Ignacio et al. discloses colorants that do not change color upon contact with hydrogen peroxide vapor (col. 3, lines 54-56). It is submitted that this is not an accurate characterization of the document. Ignacio et al. '518 at col. 3, lines 54-56 disclose that "[t]he monitor composition optionally may include other ingredients such as colorants that do not change color during *the sterilization process* . . ." (emphasis added). While the sterilization process may include other sterilants, such as hydrogen peroxide, such optional sterilants are *in addition* to peracetic acid (col. 5, lines 53-56). Ignacio et al. '518 fail to teach or suggest colorants that necessarily do not change color upon contact with hydrogen peroxide.

Again, Ignacio et al. '518 teach indicators for a sterilization process, while Davies et al. teach a disinfecting composition including a disinfecting agent, an inactivating agent, and an indicator that changes color. It is respectfully submitted that, considering the teachings of Davies et al. as a whole, the disclosure of Davies et al. is drawn to nonanalogous art from that which is pertinent to the present invention, as the present invention includes an indicator for a sterilization process, while Davies et al. disclose a contact lens disinfecting solution, wherein the disinfecting agent and the indicator must be, or be able to be rendered, ophthalmically acceptable. The disclosure of a colorant, such as brilliant green, used in a disinfection composition cannot be taken out of the context in which it is disclosed. A single statement in the prior art reference should not be taken out of context and relied upon with the benefit of hindsight to show obviousness; rather, a reference should be considered as a whole. Bausch & Lomb, Inc. v. Barnes-Hind/Hycrocurve, Inc., 796 F.2d 443, 230 U.S.P.Q. 416, 419-420 (Fed. Cir.

1986), cert. denied, 484 U.S. 823 (1987), on remand, 10 U.S.P.Q. 2d 1929 (N.D. Calif. 1989). Further, "[i]t is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art." In re Wesslau, 353 F.2d 238, 147 U.S.P.Q. 391, 393 (CCPA 1965).

For at least the above reasons, Applicant submits that one skilled in the art would not be motivated to combine the teachings of Ignacio '518 with the teachings of Davies et al.

2. Even if the teachings of Ignacio et al. '518 are combined with the teachings of Davies et al., there is no reasonable expectation of success upon such combination.

Applicant respectfully points out that the environment of the sterilization monitors of Ignacio et al. '518 are different than those of the disinfecting indictors of Davies et al. The disinfecting indicators of Davies et al. are indicators disposed in a solution. Conversely, preferred sterilant monitors of Ignacio et al. '518 contain a dye, a halogen source, and a binder resin (Ignacio et al. '518, col. 3, lines 8-9, emphasis added).

Additionally, the sterilization monitors of Ignacio et al. '518 undergo a permanent color change when exposed to a peracid, that provides an indication that sterilization has occurred (Ignacio et al. '518, col. 1, lines 29-32). That is, upon contact with the sterilization vapor, the monitor undergoes a color change that preferably does not change or fade if left exposed to normal fluorescent lights for one or two days (Ignacio et al. '518, col. 3, lines 4-7). This allows one to be certain that the indicator has been exposed to the sterilization process after the monitor has been removed from the sterilant environment.

Permanence of a color change in the monitor compositions is taught as being desirable in the sterilization monitors of Ignacio et al. '518 to indicate that articles have been exposed to a sterilization process. Conversely, such permanent color change is not specifically taught as being desirable in the indicators included in the disinfection compositions of Davies et

al. The indicators of Davies et al. change from colored to colorless upon a change of pH in solution as a result of the reduction of the hydrogen peroxide (Davies et al., col. 4, lines 4-12). That is, the indicators of Davies et al. are colored in the presence of hydrogen peroxide, and turn colorless when the disinfecting agent is deactivated, which causes a change in the pH of the solution. Such pH indicators typically return to the colored state upon further pH change, such as would occur upon re-introduction of hydrogen peroxide. Thus, although not specifically stated in Davies et al., it is Applicant's understanding that the color change of the pH indictors of Davies et al. effect a color change by a different mechanism than do the indicators of Ignacio et al. '518. Thus, the color change of the pH indictors of Davies et al. is not the "permanent" color change of the indicators of Ignacio et al. '518.

Davies et al. additionally disclose possible systems employing acid/base or redox indicators (Davies et al., col. 3, lines 29-31). While it is Applicant's Representative's understanding that redox indicators are typically reversible indicators, being one color in an oxidized state and a different color in a reduced state, redox indicators are not necessarily reversible indicators. However, considering the disclosure of Davies et al. in its entirety, considering the purpose to which the invention is directed, being the detection of hydrogen peroxide present in solution, and the analogy drawn by Davies et al. to pH indicators ("a redox indicator which preferably changes from coloured in an oxidized state to colourless when reduced" (Davies et al., col. 4, lines 4-17)), Applicant's Representative understands Davies et al. to teach a disinfection composition that includes a reversible indicator. Thus, it is submitted that no permanent color change, such as is contemplated by Ignacio et al. '518, occurs with the disinfection compositions of Davies et al. Or at least, such permanent color change is not taught as being desirable by Davies et al. as it is taught by Ignacio et al. '518.

For at least the above reasons, one skilled in the art would have no reasonable expectation whatsoever that the disclosure of Ignacio et al. '518 combined with the disclosure of Davies et al. would necessarily provide the embodiments of the present invention as claimed by Applicant.

3. It is impermissible to use hindsight as an obviousness test.

Applicants respectfully submit that the combination of Ignacio et al. '518 with Davies et al. in an obviousness rejection can only occur by the impermissible use of hindsight reasoning. In order to establish a *prima facie* case of obviousness, the references must teach or suggest all the claim limitations. Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 231 U.S.P.Q. 81 at 93 ("Focusing on the obviousness of substitutions and differences instead of on the invention as a whole, . . . was a legally improper way to simplify the difficult determination of obviousness."). One cannot "simply [to] engage in a hindsight reconstruction of the claimed invention, using the Applicant's structure as a template and selecting elements from references to fill the gaps." In re Gorman, 933 F2d 982, 18 U.S.P.Q.2d 1885, 1888 (Fed. Cir. 1991). Further, both the suggestion for combining the teachings of the prior art to make the invention and the reasonable likelihood of its success must be founded in the prior art and not in the teachings of Applicants' disclosure. In re Dow Chem., 837 F.2d 469, 473, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988). Here, the cited art neither suggests the combination of its teachings nor suggests the reasonable likelihood that such a combination would result in the present invention.

Applicants respectfully submit that there is simply no teaching, suggestion, or incentive indicated in Ignacio et al. '518 or Davies et al. that provides a motivation to combine their teachings to provide a hydrogen peroxide sterilization indicator as claimed in the present invention.

For at least the above reasons, reconsideration and withdrawal of the rejection of claims 1-2, 4-6, and 9-10 over Ignacio et al. '518 in view of Davies et al. are respectfully requested.

4. Bealing et al. and Barrett add nothing to that which is missing from Ignacio et al. '518 and Davies et al.

Applicant asserts, in view of the above comments, that the teachings of Ignacio et al. '518 may not be combined with those of Davies et al. to form the basis of an obviousness rejection. In addition, it is asserted that, with respect to claims 3, 7, and 21, Bealing et al. fail to add that which is missing from Ignacio et al. '518 or Davies et al. Also, with respect to claim 8, Bealing et al. and Barrett fail to add that which is missing from Ignacio et al. '518 or Davies et al. It is further submitted that these rejections may only be made by impermissible hindsight reconstruction, that is, by picking and choosing from each document that which supports these rejections.

Reconsideration and withdrawal of the rejections of claims 3, 7, 8, and 21 are respectfully requested.

In addition, Applicant respectfully draws the Examiner's attention to the assertion the Examiner made with respect to the recitation of the colorant Alkali blue 6B of claims 3 and 21. In the present Office Action at page 3-4, item 4, the Examiner stated that, "with respect to claims 3 and 21, Bealing et al. teaches various classes of colorant acid blue that can be used (col. 6, lines 36-38). For example, Bealing et al uses acid blue #7 or acid blue #20. Alkali blue 6B is also known as acid blue #119. Also, Bealing et al provides only examples (col. 6, lines 32-38) of using various classes of the colorant acid blue. Thus, it would have been obvious to one having ordinary skill in the art to substitute one class of acid blue for another as taught by Bealing et al (col. 6, lines 32-38)."

Applicant herein points out that Alkali blue 6B is also recited in claim 1, 10, 11, and 23. However, for at least the following reasons, Applicant asserts that Bealing et al. fail to teach or suggest the use of the colorant Alkali blue 6B (also known as acid blue #119).

As the Examiner pointed out, Ignacio et al. '518 fail to teach or suggest a composition including Alkali blue 6B. Applicant submits that Bealing et al. also do not disclose

a composition including Alkali Blue 6B, also known as Acid blue #119. As has been presented to the Examiner in, for example, the Amendment and Response Under 37 C.F.R. § 1.116, filed May 27, 2003, Bealing et al. disclose the use of Acid Blue #7 and Acid Blue #20 (column 6, lines 36-38). Acid Blue #7 has a CI 42080 and a CAS Registry No. 3486-30-4 (Exhibit A). Acid Blue #20 has a CI 50405 and a CAS Registry No. 8004-99-7 (Exhibit A). Alkali blue 6B (also known as Acid blue #119) has a CI 42750 (specification, Table, page 14, run 18, column 4) and a CAS Registry No. 1324-76-1 (Exhibit B). Each of the colorants Acid blue #7, Acid blue #20, and Acid blue #119 includes the phrase "Acid blue;" however, there is no teaching or suggestion that each colorant has the same structure or that one colorant may be successfully substituted for another. For example, the molecular formula of Alkali blue 6B (also known as Acid blue #119) is $C_{37}H_{29}N_3O_3S$ (Exhibit B), but the molecular formula of Acid Blue 7 is $C_{37}H_{35}N_2O_6S_2Na$ (Exhibit C; page 56 of the Aldrich Chemical Company Handbook of Fine Chemicals and Laboratory Equipment, 2003-2004, wherein Acid Blue #7 is listed as Alphazurine A). There is no teaching or suggestion provided that Alkali blue 6B (also known as Acid blue #119) may successfully be substituted for either Acid Blue #7 or Acid Blue #20.

The Examiner stated in the present Office Action at page 3, bridging to page 4, that Bealing et al. provide, "examples (col. 6, lines 32-38) of using various classes of the colorant acid blue. Thus it would have been obvious to one having ordinary skill in the art to substitute one class of acid blue for another one." Applicant respectfully disagrees and points out that Bealing et al. teach classes of extractable dyes including aniline dyes or sodium sulfonate salts of triphenyl methane dyes, examples of which include Acid Blue #7 (Bealing et al., col. 6, lines 32-36). Another class of extractable dye is sodium sulfonate salts of induline, such as Acid Blue #20 (Bealing et al., col. 6, lines 36-38). Applicant submits that Bealing et al. do not teach a class of dye that is an "Acid Blue" class of dyes.

Furthermore, Applicant submits that the term "Acid Blue" does not provide a means for classification of a dye. For example, Acid Blue #83 and Acid Blue #90 are methane dyes, Acid Blue #113 and Acid Blue #120 are azo dyes, and Acid Blue #25, Acid Blue #40, Acid

Blue #80, and Acid Blue #129 are anthroquinone dyes. It is, therefore, asserted that dyes including the term "Acid Blue" in their names are not necessarily interchangeable with a reasonable expectation of success. Thus, Applicant asserts that the present claims are nonobvious with respect to the art cited herein.

B. Claims 11-20

The Examiner rejected claims 11, 16, and 19-20 under 35 U.S.C. §103(a) as being unpatentable over Ignacio et al. (U.S. Patent No. 6,063,631, hereinafter "Ignacio et al. '631") in view of Malchesky et al. (U.S. Patent No. 5,518,927); claims 12-13 and 15 under 35 U.S.C. §103(a) as being unpatentable over Ignacio et al. (Ignacio et al. '631) in view of Malchesky et al. (U.S. Patent No. 5,518,927) and further in view of Ignacio et al. (Ignacio et al. '518); claim 14 under 35 U.S.C. §103(a) as being unpatentable over Ignacio et al. (Ignacio et al. '631) in view of Malchesky et al. (U.S. Patent No. 5,518,927), and further in view of Ignacio et al. (Ignacio et al. '518) and Davies et al. (U.S. Patent No. 4,863,627); claim 17 under 35 U.S.C. §103(a) as being unpatentable over Ignacio et al. (Ignacio et al. '631) in view of Malchesky et al. (U.S. Patent No. 5,518,927) and further in view of Ignacio et al. (Ignacio et al. '518) and Bealing et al. (U.S. Patent No. 5,990,199); and claim 18 under 35 U.S.C. §103(a) as being unpatentable over Ignacio et al. (Ignacio et al. '631) in view of Malchesky et al. (U.S. Patent No. 5,518,927), and further in view of Ignacio et al. (Ignacio et al. '518), Bealing et al. (U.S. Patent No. 5,990,199) and Barrett (U.S. Patent No. 5,955,025).

Applicant respectfully traverses these rejections.

Applicant respectfully asserts that the amendment of claim 11 renders moot the rejections of each of claims 11-20. Additionally, it is asserted that Malchesky et al. fail to make any specific disclosure of any other colorants recited in claim 11, as currently amended. Further, Applicant asserts that the amendment has been made solely to further prosecution of the present

application, and hereby reserves the right to traverse this rejection, and any assertions made in support of such rejection, in any continuation applications.

Furthermore, for the reasons discussed above, with respect to claim 14, it is asserted that the disclosure of Ignacio et al. '518 may not be combined with the disclosure of Davies et al. to provide an obviousness rejection. Also, neither Ignacio et al. '518 nor Davies et al. independently add that which is missing from Ignacio et al. '631 and Malchesky et al. to provide the embodiment of claim 14.

Additionally, Applicant asserts that Ignacio et al. '518 fail to add that which is missing from Ignacio et al. '631 or Malchesky et al. necessary to provide the embodiment of claims 12-13, and 15; Bealing et al. and Ignacio et al. '518 fail to add to Ignacio et al. '613 and Malchesky et al. that which is necessary to provide the embodiment of claim 17, and Ignacio et al. '518, Bealing et al., and Barrett fail to add to Ignacio et al. '631 and Malchesky et al. that which is necessary to provide claim 18.

As the Examiner required the combination of from 3 to 5 separate documents to provide rejections of the claims, Applicant asserts that these rejections could only have been made by means of impermissible hindsight reconstruction, that is, by picking and choosing from each document that which supports these rejections. One cannot "simply [to] engage in a hindsight reconstruction of the claimed invention, using the Applicant's structure as a template and selecting elements from references to fill the gaps." In re Gorman, 933 F2d 982, 18 U.S.P.Q.2d 1885, 1888 (Fed. Cir. 1991).

Reconsideration and withdrawal of these rejections are, therefore, respectfully requested.

C. Claim 23

The Examiner rejected claim 23 under 35 U.S.C. §103(a) as being unpatentable over Ignacio et al. (Ignacio et al. '631) in view of Nagata et al. (U.S. Patent No. 6,267,242) and

further in view of Bealing (U.S. Patent No. 5,990,199) and Davies et al. (U.S. Patent No. 4,863,627).

In view of the amendment of claim 23 and the Examiners statement in the Interview Summary, Applicant respectfully submits that the rejection of claim 23 is thereby rendered moot. Reconsideration and withdrawal of the rejection are, therefore, respectfully requested.

Summary

It is respectfully submitted that the pending claims 1-21 and 23 are in condition for allowance and notification to that effect is respectfully requested.

The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted for
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18 December 2003
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CERTIFICATE UNDER 37 CFR §1.8:
The undersigned hereby certifies that the Transmittal Letter and the paper(s), as described hereinabove, are being transmitted by facsimile in accordance with 37 CFR §1.6(d) to the Patent and Trademark Office, addressed to Assistant Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 18th day of December, at 6:30 pm (Central Time).

By: _____
Name: Kathleen L. Franklin

EXHIBIT A

Abbey Companies
- About Us
- Contact Us
- Driving Directions

Abbey Color
- Dye Capabilities
- Dyes for Plastics
- Eosin Dye
- Table of Dyes

Abbey Products
- Gas Leak Detection
- Gas Leak Sealant
- Concrete Repair

Abbey Concepts

Listing of Dyes at Abbey Color

Dyes for critical industrial, medical, and military applications. This is a partial list of the dyes available at Abbey Color. You may sort the list by clicking on the column heading, the list will be re-sorted by that column and re-drawn.

Abbey Product Code	Dye Type	Dye Name	Color Index	Trade Name	CAS Number	CI Number
10	Acid	Black	10	ABCOL Black 10 BR-126%	1064-48-8	20470
20	Acid	Black	2	ABCOL Nigrosine O2P	8005-03-6	50420
90	Acid	Black	24	ABCOL Milling Black 2 BNS	3071-73-6	26370
100	Acid	Black	52	ABCOL Black WA	5610-64-0	15711
1010	Direct	Black	19	ABCOL Black G	6426-31-5	35255
1080	Direct	Black	165	ABCOL Diazo Black BH-NB-125%	TOSCA #13617	None
1150	Direct	Black	170	ABCOL Black AN-NB-HC	NJ-TSRN-18881400-6003P	None
2510	Mordant	Black	11	ABCOL Chrome Black T N	1787-61-7	14645
2530	Mordant	Black	17	ABCOL Chrome Navy RZN	1787-61-7	15705
4020	Natural	Black	1	ABCOL Hematine LG	475-25-2	75290
4030	Natural	Black	1	ABCOL Hematine-HCK S	475-25-2	75290
4050	Natural	Black	1	ABCOL Hematoxylin-Certified	517-28-2	75290
5010	Solvent	Black	3	ABCOL Black X 60	4197-25-5	26150
5040	Solvent	Black	5	ABCOL Spirit Nogrosine SBDS	11099-03-9	50415
5061	Solvent	Black	7	ABCOL Nigrosine Z1630	8005-02-5	50415:1
5550	Acid	Blue	1	ABCOL Patent Blue VF	129-17-9	42045
5560	Acid	Blue	7	ABCOL Patent Blue A Conc	3486-30-4	42080
5570	Acid	Blue	9	ABCOL Blue NB	3844-45-9	42090
5600	Acid	Blue	20	ABCOL Induline Blue B X	8004-99-7	50405
5650	Acid	Blue	25	ABCOL Brilliant Blue RB	6408-78-2	62055
5660	Acid	Blue	27	ABCOL Alizarine Blue B	6408-51-1	61530
5670	Acid	Blue	29	ABCOL Blue G	5850-35-1	20460
5680	Acid	Blue	34	ABCOL Blue GOV	6460-05-5	42561
5720	Acid	Blue	281	ABCOL Blue GLF	Proprietary	None
5730	Acid	Blue	80	ABCOL Brilliant Blue RAWL	4474-24-2	61585
5750	Acid	Blue	90	ABCOL Brilliant Cyanine Blue G	6104-58-1	42655
6005	Basic	Blue	1	ABCOL Blue 6G	3251-08-0	42025
6030	Basic	Blue	7	ABCOL Victoria Blue BO	2390-60-5	42595
6050	Basic	Blue	9	ABCOL Methylene Blue 2B	61-73-4	52015
6060	Basic	Blue	9	ABCOL Methylene Blue 2B Zn Free	61-73-4	52015
6070	Basic	Blue	26	ABCOL Victoria Blue BX	2580-56-5	44045

Valid 11/1999 - 01/2000

Sigma Chemical Co.
P.O. Box 14508
St. Louis, MO 63178 USA
Tel: 314-771-5765

EXHIBIT B

MATERIAL SAFETY DATA SHEET

SECTION 1. - - - - - - - - - - CHEMICAL IDENTIFICATION- - - - - - - - - -
CATALOG #: A2931
NAME: ALKALI BLUE 6B FREE ACID

SECTION 2. - - - - - COMPOSITION/INFORMATION ON INGREDIENTS - - - - - -
CAS #: 1324-76-1
MF: C37H29N3O3S
EC NO: 215-385-2

SECTION 3. - - - - - - - - - - HAZARDS IDENTIFICATION - - - - - - - - -
LABEL PRECAUTIONARY STATEMENTS
IRRITANT
IRRITATING TO EYES, RESPIRATORY SYSTEM AND SKIN.
IN CASE OF CONTACT WITH EYES, RINSE IMMEDIATELY WITH PLENTY OF WATER AND SEEK MEDICAL ADVICE.
WEAR SUITABLE PROTECTIVE CLOTHING.

SECTION 4. - - - - - - - - - - FIRST-AID MEASURES- - - - - - - - - - -
IN CASE OF CONTACT, IMMEDIATELY FLUSH EYES WITH COPIOUS AMOUNTS OF WATER FOR AT LEAST 15 MINUTES.
IN CASE OF CONTACT, IMMEDIATELY WASH SKIN WITH SOAP AND COPIOUS AMOUNTS OF WATER.
IF INHALED, REMOVE TO FRESH AIR. IF NOT BREATHING GIVE ARTIFICIAL RESPIRATION. IF BREATHING IS DIFFICULT, GIVE OXYGEN.
IF SWALLOWED, WASH OUT MOUTH WITH WATER PROVIDED PERSON IS CONSCIOUS.
CALL A PHYSICIAN.
WASH CONTAMINATED CLOTHING BEFORE REUSE.

SECTION 5. - - - - - - - - - - FIRE FIGHTING MEASURES - - - - - - - - - -
EXTINGUISHING MEDIA
WATER SPRAY.
CARBON DIOXIDE, DRY CHEMICAL POWDER OR APPROPRIATE FOAM.
SPECIAL FIREFIGHTING PROCEDURES
WEAR SELF-CONTAINED BREATHING APPARATUS AND PROTECTIVE CLOTHING TO PREVENT CONTACT WITH SKIN AND EYES.
UNUSUAL FIRE AND EXPLOSIONS HAZARDS
EMITS TOXIC FUMES UNDER FIRE CONDITIONS.

SECTION 6. - - - - - - - - - ACCIDENTAL RELEASE MEASURES- - - - - - - - -
WEAR SELF-CONTAINED BREATHING APPARATUS, RUBBER BOOTS AND HEAVY RUBBER GLOVES.
SWEEP UP, PLACE IN A BAG AND HOLD FOR WASTE DISPOSAL.
AVOID RAISING DUST.
VENTILATE AREA AND WASH SPILL SITE AFTER MATERIAL PICKUP IS COMPLETE.

SECTION 7. - - - - - - - - - - HANDLING AND STORAGE- - - - - - - - - - -
REFER TO SECTION 8.

SECTION 8. - - - - - - EXPOSURE CONTROLS/PERSONAL PROTECTION- - - - - -
CHEMICAL SAFETY GOGGLES.
RUBBER GLOVES.
NIOSH/MSHA-APPROVED RESPIRATOR.
SAFETY SHOWER AND EYE BATH.
MECHANICAL EXHAUST REQUIRED.

AVOID CONTACT AND INHALA N.
DO NOT GET IN EYES, ON SKIN, ON CLOTHING.
WASH THOROUGHLY AFTER HANDLING.
IRRITANT.
KEEP TIGHTLY CLOSED.
STORE IN A COOL DRY PLACE.

SECTION 9. - - - - - - - PHYSICAL AND CHEMICAL PROPERTIES - - - - - - -

APPEARANCE AND ODOR
BLUE SOLID

SECTION 10. - - - - - - - - -STABILITY AND REACTIVITY - - - - - - - - -

INCOMPATIBILITIES
STRONG OXIDIZING AGENTS

HAZARDOUS COMBUSTION OR DECOMPOSITION PRODUCTS
TOXIC FUMES OF:
CARBON MONOXIDE, CARBON DIOXIDE
NITROGEN OXIDES
SULFUR OXIDES

SECTION 11. - - - - - - - - - TOXICOLOGICAL INFORMATION - - - - - - - -

ACUTE EFFECTS
MAY BE HARMFUL BY INHALATION, INGESTION, OR SKIN ABSORPTION.
CAUSES EYE AND SKIN IRRITATION.
MATERIAL IS IRRITATING TO MUCOUS MEMBRANES AND UPPER RESPIRATORY TRACT.
TO THE BEST OF OUR KNOWLEDGE, THE CHEMICAL, PHYSICAL, AND TOXICOLOGICAL PROPERTIES HAVE NOT BEEN THOROUGHLY INVESTIGATED.

SECTION 12. - - - - - - - - - ECOLOGICAL INFORMATION - - - - - - - - -

DATA NOT YET AVAILABLE.

SECTION 13. - - - - - - - - - DISPOSAL CONSIDERATIONS - - - - - - - - -

DISSOLVE OR MIX THE MATERIAL WITH A COMBUSTIBLE SOLVENT AND BURN IN A CHEMICAL INCINERATOR EQUIPPED WITH AN AFTERBURNER AND SCRUBBER.
OBSERVE ALL FEDERAL, STATE AND LOCAL ENVIRONMENTAL REGULATIONS.

SECTION 14. - - - - - - - - - - TRANSPORT INFORMATION - - - - - - - - -

CONTACT SIGMA CHEMICAL COMPANY FOR TRANSPORTATION INFORMATION.

SECTION 15. - - - - - - - - - REGULATORY INFORMATION - - - - - - - - -

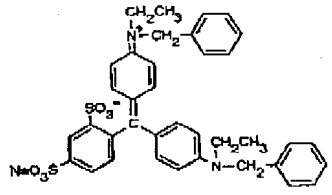
EUROPEAN INFORMATION
IRRITANT
R 36/37/38
IRRITATING TO EYES, RESPIRATORY SYSTEM AND SKIN.
S 26
IN CASE OF CONTACT WITH EYES, RINSE IMMEDIATELY WITH PLENTY OF WATER AND SEEK MEDICAL ADVICE.
S 36
WEAR SUITABLE PROTECTIVE CLOTHING.

SECTION 16. - - - - - - - - - - OTHER INFORMATION- - - - - - - - - - -

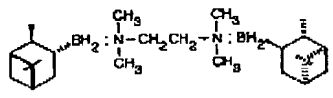
THE ABOVE INFORMATION IS BELIEVED TO BE CORRECT BUT DOES NOT PURPORT TO BE ALL INCLUSIVE AND SHALL BE USED ONLY AS A GUIDE. SIGMA, ALDRICH, FLUKA SHALL NOT BE HELD LIABLE FOR ANY DAMAGE RESULTING FROM HANDLING OR FROM CONTACT WITH THE ABOVE PRODUCT. SEE REVERSE SIDE OF INVOICE OR PACKING SLIP FOR ADDITIONAL TERMS AND CONDITIONS OF SALE.

■ Allylurea ■

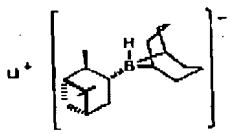
				US $
A3,680-8 ★	**Allylurea**, 95% [*557-11-9*] $H_2C{=}CHCH_2NHCONH_2$ FW 100.12 mp 84-86° *Bell.* 4,209. *Merck Index* 13,295 *FT-NMR* 1(1),1308B *FT-IR* 1(1),800D *Safety* 2,107D *R&S* 1(1),939M *RTECS*® YR7875000		25g 100g 250g	21.20 58.50 128.60
19,814-5 ★	**Alphazurine A** [*3486-30-4*] (Acid Blue 7, C.I. 42080, Patent Blue A) FW 690.82 mp 290°(dec.) λmax 637(409)nm *Beil.* 14,856 *FT-IR* 1(2),1031A *Safety* 2,108B *R&S* 1(2),2779L *UV-Vis* 87 *RTECS*® DA4427950 Dye content ~60%		25g 100g	29.40 63.90
	Alphazurine FG, see 86,114-6, Erioglaucine page 820			
25,149-6	*R*-**Alpine-Boramine™** [*67826-92-0*] [*N,N'*-bis(monoisopinocampheylborane)-*N,N,N',N'*-tetramethylethylenediamine]FW 416.36 mp 143-144° *Safety* 2,106D *R&S* 1(2),3033B *FLAMMABLE SOLID MOISTURE-SENSITIVE* Chiral hydroboration reagent. *J. Org. Chem.* **1980**, *45*, 3543. For further references, see *Aldrichimica Acta* **1987**, *20*, 30. Derived from (+)-α-pinene		5g 25g	47.30 151.10
49,579-4	*S*-**Alpine-Boramine™** [*68297-74-5*] [*N,N'*-bis(monoisopinocampheylborane)-*N,N,N',N'*-tetramethylethylenediamine]FW 416.36 mp 144-146° *FLAMMABLE SOLID MOISTURE-SENSITIVE* Chiral hydroboration reagent. *J. Org. Chem.* **1980**, *45*, 3543. For further references, see *Aldrichimica Acta* **1987**, *20*, 30.		5g 25g	38.10 126.60
41,720-3	*R*-**Alpine-Borane®**, 97% [*73624-47-2*] (*B*-isopinocampheyl-9-borabicyclo[3.3.1]nonane) FW 258.26 bp >55° d 0.947 $[\alpha]^{21}$ -22° (c=12, THF) *PYROPHORIC* Derived from (+)-α-pinene		25mL	203.60
23,273-4	*R*-**Alpine-Borane®** [*73624-47-2*] (*B*-isopinocampheyl-9-borabicyclo[3.3.1]-nonane, 0.5*M* solution in tetrahydrofuran) FW 258.26 d 0.896 Fp 1°F(-17°C) $[\alpha]^{5}$ -3.0° (neat) *Fieser* 8,403 10,320 11,429 *Safety* 2,109A *FLAMMABLE LIQUID IRRITANT* *R*- and *S*-Alpine-Boranes are used for asymmetric reduction of aldehydes[1,2] and prochiral ketones.[2,3] (1) *Synlett* **1993**, 561. (2) *Tetrahedron: Asymmetry* **1994**, *5*, 1061, 1075. *Aldrichimica Acta* **1987**, *20*, 30. (3) *ibid.* **1982**, *15*, 68. Derived from (+)-α-pinene (*Packaged under nitrogen in Sure/Seal™ bottles*)		100mL 800mL	67.90 293.40
41,704-1	*S*-**Alpine-Borane®**, 97% [*42371-63-1*] (*B*-isopinocampheyl-9-borabicyclo[3.3.1]nonane) FW 258.26 bp >55° d 0.947 $[\alpha]^{22}$ +20° (c=12, THF) *PYROPHORIC* Derived from (-)-α-pinene		25mL	220.30
23,770-1	*S*-**Alpine-Borane®** [*42371-63-1*] (*B*-isopinocampheyl-9-borabicyclo[3.3.1]-nonane, 0.5*M* solution in tetrahydrofuran) FW 258.26 d 0.897 Fp 1°F(-17°C) $[\alpha]^{22}$ +1.2° (neat) *Fieser* 8,403 11,429 *Safety* 2,109B *FLAMMABLE LIQUID* See 23,273-4 above. Derived from (-)-α-pinene (*Packaged under nitrogen in Sure/Seal™ bottles*)		100mL 800mL	68.00 294.90
22,902-4	*R*-**Alpine-Hydride®** [*64081-12-5*] (lithium *B*-isopinocampheyl-9-bora-bicyclo[3.3.1]nonyl hydride, 0.5*M* solution in tetrahydrofuran) FW 266.21 d 0.919 Fp 1°F(-17°C) $[\alpha]^{5}$ -5.6° (neat) *Fieser* 8,303 *Safety* 2,109C *FLAMMABLE LIQUID MOISTURE-SENSITIVE* (*Packaged under nitrogen in Sure/Seal™ bottles*)		100mL	61.20
23,772-8	*S*-**Alpine-Hydride®** [*100013-07-8*] (lithium *B*-isopinocampheyl-9-bora-bicyclo[3.3.1]nonyl hydride, 0.5*M* solution in tetrahydrofuran) FW 266.21 d 0.920 Fp 1°F(-17°C) $[\alpha]^{5}$ +5.5° (neat) *Fieser* 8,303 *Safety* 2,109D *FLAMMABLE LIQUID MOISTURE-SENSITIVE* (*Packaged under nitrogen in Sure/Seal™ bottles*)		100mL	66.10
	ALTRETAMINE, see 54,963-5, 2,4,6-Tris(dimethylamino)-1,3,5-triazine page 1887			
	Alum, see Aluminum potassium sulfate dodecahydrate			



19,814-5



25,149-6



22,902-4

47,739-7	**Alumatrar**	FW 692.6 May conta Licensed
23,404-4	**Alum Cat**	
51,774-7 ★	**Alumina,**	*Merck In* Average
51,775-5 ★	**Alumina,**	*Merck In* Average
	Alumina	
A3,688-3 ★	**Alumino**	FW 473. *FT-IR* 1(Reagent May con Ignitior Sensiti
45,403-6 ★	**Alumino**	May cor
54,104-4	**Alumin**	*Merck*
42,480-3 ★	**Alumin**	d 2.70(
43,370-5 ★	**Alumin**	[*7429-* Weight
43,371-3 ★	**Alumir**	Al Weight
51,857-3 ★	**Alumi**	
51,858-1 ★	**Alumi**	*RTEC*
26,659-0 ★	**Alumi**	13.6g
26,695-7 ★	**Alumi**	6.8g=
26,657-4 ★	**Alum**	3.4g=
32,685-2 ★	**Alum**	1.7g
26,658-2 ★	**Alum**	6.8g
32,686-0 ★	**Alum**	900
35,685-9 ★	**Alum**	3.1g
32,692-5 ★	**Alur**	
51,860-3 ★	**Alu**	*Me*

EXHIBIT C